

PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: | Tedesco et al. | Art Unit: | 1644 |
| Serial No.: | 10/521,109 | Examiner: | Francois P. Vandervegt |
| Filed: | January 11, 2005 | Customer No.: | 21559 |
| Confirmation No.: | 5428 | | |
| Title: | Antibodies Anti-C5 Component of the Complement System and Their Use | | |

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO RESTRICTION REQUIREMENT

In reply to the Restriction Requirement that was mailed in connection with the above-captioned case on July 5, 2007, applicant elects the invention of Group I, claims 37-49, 56 and 58. The election is made with traverse.

Applicants note that the present US Application is the National phase of a PCT Application.

According to the decision in *Caterpillar Tractor Company v. Commissioner of Patents and Trademarks* , 231 U.S.P.Q. 590 (E.D. Va. 1986), when the USPT Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111.

According to PCT Rules 13.1 and 13.2 unity of invention for claims of different categories such as :

- a product X,
- a method of manufacturing the product X, and
- method of use product X,

exists if the substance X is not known in the art (see Example 1 concerning Unity of Invention, p. 80 of the “PCT International search and Preliminary Examination Guidelines, as in force from March 25, 2004, enclosed for the examiner’s convenience).

In the instant case:

- product X is the human antibody specific for the region 731-740 of the C5 component of the human complement and corresponds to Group I as identified in the Official Action (claims 37-49, 56 and 58),
- the method of manufacturing such antibody is defined by claim 71, corresponding to Group VIII,
- a method of use of such antibody in the therapeutic treatment or prevention of diseases involving hyperactivation of the complement system, is defined by claims 60, 62, 64 and 66, corresponding to Group III.

The Examiner has alleged lack of novelty of the present human antibody specific for the region 731-740 of the C5 component of the human complement, over the disclosure of Fitch (Circulation [1999] 100:2499-2506).

The Applicant respectfully disagrees for the following reasons:

- 1) Fitch describes a “humanized” antibody while the present antibody is a human antibody (i.e. it belongs to the human antibodies repertoire and, as such, is not likely to elicit any immune response when used in human therapy),

2) Fitch does not describe the specificity of the antibody which is to recognize the epitope comprised in the 731-740 aa region of the C5 component of the human complement. This feature (the recognized epitope) is novel and is typical for an antibody even more than the structural features of the antibody itself.

According to the above considerations, the human antibody disclosed in the Application is new and the Applicant requests that the PCT criteria of unity of invention would be applied so as to recognize the same special technical feature underlying inventions belonging to Groups I, III and VIII.

Finally, Applicants note that it seems that Group IV and VI identify the same invention. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: September 5, 2007

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